510(k) SUMMARY

K093507

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CHF-Y0003
CHOLEDOCHO VIDEOSCOPE

November 6, 2009

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1 General Information

- Applicant: OLYMPUS MEDICAL SYSTEMS CORP.
  2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507
  Establishment Registration No: 8010047

- Official Correspondent: Stacy Abbatiello Kluesner, M.S., RAC
  Regulatory Affairs & Quality Assurance
  Olympus America Inc.
  3500 Corporate Parkway
  PO Box 610
  Center Valley, PA 18034-0610, USA
  Phone: 484-896-5405
  FAX: 484-896-7128
  Email: stacy.kluesner@olympus.com

- Manufacturer: Olympus Medical Systems Corp.
  Hinode Plant
  34-3 Hirai, Hinode-cho, Nishitama-gun, Tokyo 190-0182,
  Tokyo, 192-8507, Japan

2 Device Identification

- Device Trade Name: CHF-Y0003
- Common Name: CHOLEDOCHO VIDEOSCOPE
- Regulation Number: 21 CFR 876.1500
- Regulation Name: Endoscope and accessories
- Regulatory Class: II
- Classification Panel: Gastroenterology/Urology
- Product Code: FBN – Choledochoscope, accessories
  NWB - Endoscope, accessories, narrow band spectrum

3 Predicate Device Information

- Device Name: CHF-V

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- Common Name: CHOLEDOCHO VIDEOSCOPE
- Manufacturer: Aizu Olympus Co., Ltd.
  500 Aza-Muranishi, Ooaza-Iidera, Monden-cho,
  Aizuwakamatsu-shi, Fukushima, Japan 965-8520
  Establishment Registration No.: 9610595
- 510(k) No. K081456

4 Device Description

The CHF-Y0003 choledochoscope is a flexible video endoscope used for endoscopic diagnosis and treatment within the bile duct through a percutaneous route and/or intraoperatively, utilized with the EVIS EXERA II 180 System. The CHF-Y0003 choledochoscope is basically identical to the predicate device, CHF Type V, in specifications, performance, and optical system.

The differences of the subject CHF-Y0003 from the predicate device CHF-V are as follows:

- The material of the bending rubber in the bending section is different.
- Indication for use has been changed to include a percutaneous route and/or intraoperatively use to specify the applied part.

5 Indications for Use

This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bile duct through a percutaneous route and/or intraoperatively.

6 Comparison Between the Predicate Device

The CHF-Y0003 is basically identical to the predicate device in intended use, except the addition of a percutaneous route and/or intraoperatively use, and identical in specifications except the material. The clinical literatures provided in this submission supports the safety and efficacy of the choledochoscope used in a percutaneous route and/or intraoperatively. Test data of the biocompatibility testing provided in this submission supports the safety and efficacy of the new material.

7 Conclusion

When compared to the predicate device, the CHF-Y0003 does not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Olympus Medical System Corp.
% Stacy Abbatiello Kluesner
Project Manager
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3500 Corporate Parkway PO Box 610
CENTER VALLEY PA 18034-0610

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Re: K093507
Trade/Device Name: CHF-Y0003
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FBN, NWB
Dated: November 6, 2009
Received: November 13, 2009

Dear Ms. Kluesner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

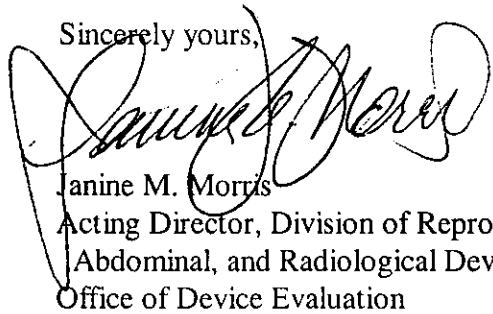
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093507

Device Name: **CHF-Y0003**

Indications For Use:

This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bile duct through a percutaneous route and/or intraoperatively.

Prescription Use ✓ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093507